

REMARKS

Status of the Claims

Claims 1, 3, 5-7, 9-21 and 46-50 are pending in this application. Claims 2, 4, 8 and 22-45 have been canceled. Claims 46-50 have been amended to correct a misspelling. No new matter has been added. Thus, Claims 1, 3, 5-7, 9-21 and 46-50 are presented for examination.

Withdrawal of the Rejection Under 35 U.S.C. §103(a) Based on CLERC and BOLZ

Applicant acknowledges with thanks the withdrawal of the rejection of Claims 1, 3, 5-7, 9-21 and 46-48 under 35 U.S.C. 103(a) based on Clerc, U.S. Application Publication No. 2002/0165601 (“CLERC”) in view of Bolz et al., U.S. Patent No. 6,287,332 (“BOLZ”).

New Rejection Under 35 U.S.C. §103(a) Based on HOGANSON in View of BOLZ

The Examiner has rejected Claims 1, 3, 5-7, 9-21 and 46-50 under 35 U.S.C. 103(a) based on Hoganson et al., U.S. Application Publication No. 2003/0074049 (“HOGANSON”) in view of BOLZ. This rejection is respectfully traversed.

For a proper obviousness rejection, the differences between the subject matter sought to be patented and the prior art must be such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. MPEP 2141. “ ‘[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.’ ” *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, 82 USPQ2d 1385 (2007), quoting *In re Kahn*, 441 F.3d 977, 988, (Fed. Cir. 2006). In addition, there must be a reasonable expectation of success. See MPEP 2143.02.

HOGANSON describes a covered stent for use in a vessel, duct, lumen or hollow organ of a living being. The covered stent includes a stent or framework of interconnected elongated members in the form of a hollow tube having an inner surface

and an outer surface. The stent may be a coiled stent, slotted tube stent, self-expanding stent, or any other intravascular stent design and may be metal or a polymer or a combination.

It should be noted that there is some confusion in HOGANSON as to the placement of a cover relative to the stent. The Abstract in HOGANSON states that “*A cover is disposed over a portion of the stent, either on the inside surface, the outside surface or intermediate those surfaces.*” (emphasis added). But the embodiments described in paragraphs 26-29 recite that “*The cover is disposed over at least one of the surfaces of the hollow tubular framework or within the interstices*”. (emphasis added). Moreover, even in the latter case, covering the interstices is an *alternative* to covering the inside and/or outside surface of the stent. In the present invention, on the other hand, the covering material completely covers the biodegradable core material.

The cover in HOGANSON may be a polymer and may be resorbable. The cover can be attached to the stent by wrapping a sheet of polymer material around the stent, or forming a tube of polymer material and mounting it over the stent. The cover can extend over the entire stent or only a portion of the stent and may include one or more drugs or other beneficial active agents for delivery into the body of the being. Moreover, the cover may have properties to prevent permanent occlusion of a side-branch or bifurcation when placed within a branching or bifurcated vessel and may be constructed to selectively perforate or otherwise provide an opening to allow flow in a side-branch or bifurcated vessel.

HOGANSON does not teach or disclose the present invention which provides:

An implantable or insertable medical device adapted to provide a controlled change in mechanical properties and biomechanical compatibility after being implanted or inserted into a patient comprising a biodegradable inner core material and a biodegradable covering material completely covering the inner core material; wherein the biodegradable inner core material is selected from a metallic material and a ceramic material, wherein the covering material substantially controls the rate at which the inner core material becomes flexible upon contact with bodily fluids, wherein after insertion or implantation into a patient, the medical device becomes decreasingly rigid and increasingly biomechanically compatible with body tissue in contact with the device over time, wherein said biodegradable covering material does not contain therein a therapeutic agent, and wherein the medical device is substantially biodegradable by the body.

More particularly, HOGANSON describes the flexibility of its stents as follows:

The stent cover is preferably very flexible as to not impact the flexibility of the stent or overall stent system and for applications where the stent is to expand is preferably very plastic and/or elastic so it can expand as the stent is deployed. (See paragraph 134) (emphasis added).

In HOGANSON the stent cover starts off as being very flexible. There is no modification of the flexibility via a covering of an inner core over the period that the covering is contacted with bodily fluid. There is no description or suggestion regarding the use of any covering to modify the flexibility of the medical device as described for the present invention. In fact, the cover preferably has no impact of the flexibility of the stent whatsoever.

HOGANSON discusses modification of flexibility at paragraph 82 as related to Fig. 3 and the use of exterior longitudinal structures:

In particular in FIG. 3 there is shown a covered stent 50 constructed similarly to stent 10, i.e., having a stent body or framework 20 but having a different cover 52. In this embodiment the cover 52 comprises three different materials 52a, 52b, and 52c mounted on the exterior surface of the stent 20 in respective longitudinally located sections of the cover. One or more materials can be used along the length of the cover to vary the mechanical or other properties of the cover. A cover material which is thinner or more elastic at the ends of the stent can allow the ends of the stent to expand first and provide a mechanical seal to prevent extrusion of the lesion out of the ends of the stent when the middle of the stent expands. Thus, the sections 52a and 52c can be made thinner than section 52b of the cover.

This approach by HOGANSON is not relevant to the present invention and, in fact, teaches away from complete coverage of the inner core material, instead preferring longitudinal structures on only the abluminal (vessel contacting) surface of the stent, none of which structures are indicated as being bioerodable.

This is also the case with the paragraphs from HOGANSON cited by the Examiner in the current OA:

First, contrary to the Examiner's position, paragraphs 70, 72, 78 and 85 do not specifically describe any covering of the inner core of a stent which results in complete coverage of the inner core as is required by the present invention. Further, the element 22 of HOGANSON as seen in Figs. 2c and 6a does not show complete coverage as required by the present invention.

Second, the Examiner admits that HOGANSON also fails to disclose the biodegradable inner core material as being specifically selected from biodegradable metallic and ceramic materials.

The Examiner then goes on to discuss the concept of hydrophobic surface erodible polymers as exemplified in Table 2 of HOGANSON. This concept is included in Claims 5 and 48-50 of the present invention which describes the inclusion of a hydrophobic surface erodable polymer as a covering material (Claim 5), and more particularly, the use of a polyamide, a polyorthoester or a polyanhydride as a covering material (Claims 48-50). There is no teaching or suggestion in HOGANSON, however, of using such materials to completely cover the inner core material as claimed, much less for purposes of modifying the flexibility of the medical device.

The Examiner then turns to BOLZ as teaching constructing a bioresorbable stent of degradable metallic materials. BOLZ describes an implantable, bioresorbable vessel wall support, in particular a coronary stent, comprising a combination of metal materials which dissolves harmlessly in the human body. The combination of metal materials can be an alloy or a local galvanic element (see Abstract). The only coating described in BOLZ is a protective oxide coat (see col. 2, lines 27-28). There is no teaching or suggestion of any polymer coating for any purpose in BOLZ at all (much less a hydrophobic surface erodable polymer as claimed in certain claims Claims 5 and 48-50) and, thus, BOLZ is not combinable with HOGANSON.

Indeed, BOLZ fails to teach or suggest a biodegradable covering material of any type that completely covers an inner core material as claimed.

The Examiner also comments that for Claims 7, 10, 49 and 50, that it would be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. This, however, is a mere conclusory statement, without articulated reasoning with some rational underpinning to support the legal conclusion of obviousness, which is prohibited by *KSR* (see above). This reasoning also fails since BOLZ does not describe the use of any polymer coating at all, so the logic of combining BOLZ with HOGANSON would not even lead one skilled in the art to make the choices alleged by the Examiner.

The Examiner's comments on Claims 11-14 include the statement that HOGANSON fails to disclose that the inner core is a monofilament core or a multi-filament core comprising woven or braided filaments. The Examiner again relies on the argument that these would have been obvious choices and that such structures would have the same performance as the tubular structures described by HOGANSON. Again, the Examiner has failed to provide any logic for this assertion. This is not the applicable standard:

A statement that modifications of the prior art to meet the claimed invention would have been “‘well within the ordinary skill of the art at the time the claimed invention was made’” because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references. *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993). *’[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.’” *KSR*, 550 U.S. at ___, 82 USPQ2d at 1396 quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). MPEP 2143.

The Examiner has not met this standard.

With regard to the Examiner's comments on Claims 15 and 19-21, it is respectfully submitted that these rejections are overcome for the reasons discussed above.

With regard to the Examiner's comments Claims 46 and 47, attention is again called to the lack of any teaching or suggestion in either or both of HOGANSON and BOLZ as discussed above concerning any modification of flexibility as described for the present invention.

For at least the above reasons, reconsideration and withdrawal of this rejection under 35 U.S.C. 103(a) are thus respectfully requested.

CONCLUSION

Applicants submit that Claims 1, 3, 5-7, 9-21 and 46-50 are in condition for allowance, early notification of which is earnestly solicited. Entry of this Amendment and Response is respectfully requested as it will put the case in a form for allowance or in better form for an appeal. It is believed that this Amendment and Response is being submitted in time for an Advisory Action should the Examiner require further changes to the Claims. Should the Examiner be of the view that an interview would expedite consideration of this Response or of the application at large, the Examiner is requested to

USSN 10/075,970

Attorney Docket Number 01-202

telephone the Applicant's attorney at the number listed below in order to resolve any outstanding issues in this case.

Respectfully submitted,

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Dated: August 31, 2009